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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,903	03/15/2004	David F. Duncan	VTN-5019	1475
27777	7590	05/19/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			WEST, PAUL M	
			ART UNIT	PAPER NUMBER
			2856	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

EJC

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/800,903	DUNCAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul M. West	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09172004</u> .  | 6) <input type="checkbox"/> Other: ____                                     |

## **DETAILED ACTION**

### ***Specification***

Claim 6 is objected to because of the following informalities: the term "on" in the second line appears to be incorrect and should most likely be replaced by -- one --. Appropriate correction is required.

Claim 18 is objected to because of the following informalities: the term "of" appearing in line 3 of the last page of the disclosure appears to be incorrect and should most likely be omitted. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, 10, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 7 and 8, the phrase "said packages" lacks antecedent basis since "at least one package" is the only basis set forth in either claim.

As to claim 10, the first fixed distance of "30%" is indefinite because the claim does not indicate what larger distance the first fixed distance is a percentage of. Also, the phrase "about 0" is unclear because the first fixed distance cannot be less than 0 and anything greater than 0 would be included in the range of 0 to 30%.

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As to claim 14, the phrase, "reduced to about greater than or equal to -70 kPa," is unclear because not all values that are greater than -70 kPa would be reached by reducing the pressure from atmospheric (i.e. values that are greater than atmospheric pressure are also greater than -70 kPa).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 5, 6, 12, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Fraim et al.

As to claims 1 and 3, Fraim et al. teach an apparatus for detecting leaks in a sealed package 100 with a closure 105 that is deformable when subjected to an air pressure below atmospheric pressure, the apparatus comprising: a chamber 300 that may be opened and closed to allow for loading and unloading, and wherein the chamber 300 when closed can be evacuated or returned to atmospheric pressure (Col. 6, lines 32-34); a plurality of mechanical switches 340,425 that inherently have a head, a tail and a sensor, wherein the head is located a first fixed distance from the deformable closure, and the tail is located a second fixed distance from the sensor when the chamber is closed at

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atmospheric pressure (see Fig. 3); and a mechanism 335 for determining whether the mechanical switches are open or closed.

As to claims 4 and 5, Fraim et al. teach the sensor being a laser or a non-contact capacitive proximity sensor (Col. 6, lines 21-25).

As to claim 6, Fraim et al. teach the chamber 300 comprising a first floor 405 and a second floor 410 wherein the second floor comprises a plurality of mechanical switches 425.

As to claim 12, Fraim et al. teach a method for detecting leaks in a sealed package 100 which comprises a closure 105 that is deformable when subjected to an air pressure below atmospheric pressure, the method comprising: loading the package 100 to a chamber 300 that may be opened and closed to allow for loading and unloading (Col. 6, lines 6-7), wherein the chamber 300 when closed can be evacuated or returned to atmospheric pressure (Col. 6, lines 32-34), and wherein the chamber 300 comprises a plurality of mechanical switches 340,425 that inherently have a head, a tail and a sensor, wherein the head is located a first fixed distance from the deformable closure, and the tail is located a second fixed distance from the sensor when the chamber is closed at atmospheric pressure (see Fig. 3); closing the chamber 300 and reducing the pressure in the chamber 300 to a level below the internal pressure of the package 100 and its contents (Col. 6, lines 31-33); determining whether the mechanical switches 340,425 are open or closed (Col. 6, lines 41-43).

As to claim 14, Fraim et al. teach reducing the pressure to  $-4$  psig (4 psi below atmospheric pressure) which is approximately  $-27.58$  kPa, which is greater than  $-70$  kPa.

As to claim 18, Fraim et al. teach a method for detecting leaks in a sealed package 100 which comprises a closure 105 that is deformable when subjected to an air pressure below atmospheric pressure, the method comprising: loading the package 100 to a chamber 300 that may be opened and closed to allow for loading and unloading (Col. 6, lines 6-7), wherein the chamber 300 when closed can be evacuated or returned to atmospheric pressure (Col. 6, lines 32-34), and wherein the chamber 300 comprises a plurality of mechanical switches 340,425 that inherently have a head, a tail and a sensor, wherein the head is located a first fixed distance from the deformable closure, and the tail is located a second fixed distance from the sensor when the chamber is closed at atmospheric pressure (see Fig. 3); closing the chamber 300 and increasing the pressure in the chamber 300 to a level above the internal pressure of the package 100 and its contents (Col. 6, lines 26-30); reducing the pressure in the chamber 300 to a level below the internal pressure of the package 100 and its contents (Col. 6, lines 31-33); determining whether the mechanical switches 340,425 are open or closed (Col. 6, lines 41-43).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 11, 13, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraim et al.

As to claims 8 and 13, Fraim et al. teach all of the limitations as set forth above but do not specifically point to the apparatus or method being used to test ophthalmic lens packages. However, because the apparatus and method of Fraim is inherently capable of being used to test ophthalmic lens packages, it would have been obvious to one of ordinary skill in the art to use them for this purpose.

As to claim 11, Fraim et al. teach all of the limitations as set forth above but do not explicitly teach the tail of the mechanical switch being a distance from the sensor equal to the sum of the maximum amount the deformable closure moves + 80% of the sensing range. It would have been obvious to one of ordinary skill in the art to use this fixed distance because it allows the mechanical switch to operate within the sensing range of the sensor. Note that Applicant does not point out any benefit of this particular fixed distance over any other fixed distance that allows the switch to operate within the sensing range of the sensor, and therefore any such distance is equally obvious.

As to claims 16 and 17, Fraim et al. teach all of the limitations as set forth above but do not mention the amount of time it takes to complete the method. However, it would have been obvious to one of ordinary skill in the art to

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complete the method in less than 10 seconds, less than 5 seconds, or in any relatively short period of time, because it allows for greater efficiency and productivity in a manufacturing environment.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fraim et al. in view of Stauffer et al.

As to claim 7, Fraim et al. teach all the limitations as set forth above but do not teach the first lower floor comprising molded indentations for holding the packages. Stauffer et al. teach a leak detection apparatus with a first lower floor 37 comprising a molded indentation 38 for holding the package 2. It would have been obvious to one of ordinary skill in the art to employ the molded indentation of Stauffer in the apparatus of Fraim because it would provide support and stabilization for the base and sides of the package during pressurization and evacuation of the chamber.

Claims 2, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraim et al. in view of Croce.

As to claims 2, 9, and 10, Fraim et al. teach all of the limitations as set forth above and also teach a first floor 405 and a second floor 410, wherein the second floor comprises a plurality of mechanical switches 425 and port which attaches vacuum line 420 (see Fig. 4A). Fraim et al. do not teach the head of the mechanical switch being positioned on the surface of the deformable closure, when the chamber is closed under atmospheric pressure, nor do they specify the



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fixed distance the head should be from the deformable closure. Croce teaches an apparatus and method for detecting leaks in a sealed package 20 with a deformable closure 19, wherein the package 20 is placed in a chamber 11, and the head 14 of a mechanical switch 12 is positioned on the surface of the deformable closure 19 when the chamber 11 is closed under atmospheric pressure (Col. 4, lines 24-27). It would have been obvious to one of ordinary skill in the art to use the teachings of Croce with the apparatus of Fraim because the only way to ensure that a mechanical switch is actuated by the moving deformable closure is by positioning the head of the switch directly against the surface of the closure.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fraim et al. in view of Perhach et al.

As to claim 15, Fraim et al. teach all the limitations as set forth above but do not teach the head of the mechanical switch being spring loaded against the surface of the deformable closure when the chamber is closed under atmospheric pressure. Perhach et al. teach the head 62 of a mechanical switch 69 being spring loaded by means of spring 60 against the surface of a deformable closure 41 in a chamber 25 that is closed under atmospheric pressure (Col. 6, lines 31-34). It would have been obvious to one of ordinary skill in the art to employ the teachings of Perhach with the method and apparatus of Fraim because using a spring loaded head ensures that the head will remain in

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contact with the deformable closure as the closure moves and thus enables continuous monitoring of the closure's displacement.


### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note that Mally et al. employ multiple mechanical sensors that extend through a top floor and into a vacuum chamber. Note that Massage employs multiple mechanical sensors in contact with the deformable closures of packages in a vacuum chamber.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul M. West whose telephone number is (571) 272-8590. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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